CLAIMS

What is claimed is:

1. An isolated GB1 domain polypeptide which exhibits binding activity for a Fab fragment of an IgG but exhibits substantially no binding activity for a Fc fragment of an IgG.

2. The isolated GB1 domain polypeptide of claim 1, further comprising a disassociation constant for a Fc fragment of an IgG of greater than about 2 mM.

3. The isolated GB1 domain polypeptide of claim 1, further comprising a disrupted "knobs-into-holes" binding site for a Fc fragment of an IgG.

4. The isolated GB1 domain polypeptide of claim 3, further comprising a mutation at a "knobs-into-holes" binding site for a Fc fragment of an IgG, the mutation comprising an amino acid substitution.

5. The isolated GB1 domain polypeptide of claim 4, wherein the amino acid substitution comprises a comparatively non-polar amino acid residue in place of a polar amino acid residue.

6. The isolated GB1 domain polypeptide of claim 4, further comprising a mutation at the glutamate 27 residue of a native GB1 domain polypeptide, the mutation comprising an amino acid substitution of the glutamate 27 residue.

7. The isolated GB1 domain polypeptide of claim 6, having an amino acid sequence essentially as set forth in any SEQ ID NO:6, 20, 22 and 24.

8. The isolated GB1 domain polypeptide of claim 4, further comprising a mutation at a lysine 28 residue of a native GB1 domain polypeptide, the mutation comprising an amino acid substitution of the lysine 28 residue.

9. The isolated GB1 domain polypeptide of claim 8, wherein the mutation comprises substitution of the lysine 28 residue with a comparatively non-polar amino acid residue.

10. The isolated GB1 domain polypeptide of claim 9, wherein the non-polar amino acid residue is selected from the group consisting of alanine, valine, leucine and isoleucine.

11. The isolated GB1 domain polypeptide of claim 10, having an amino acid sequence essentially as set forth in SEQ ID NO:8.

12. The isolated GB1 domain polypeptide of claim 4, further comprising a mutation at a lysine 31 residue of a native GB1 domain polypeptide, the mutation comprising an amino acid substitution of the lysine 31 residue.

13. The isolated GB1 domain polypeptide of claim 12, wherein the mutation comprises substitution of the lysine 31 residue with a comparatively non-polar amino acid residue.

14. The isolated GB1 domain polypeptide of claim 13, wherein the non-polar amino acid residue is selected from the group consisting of alanine, valine, leucine and isoleucine.

15. The isolated GB1 domain polypeptide of claim 14, having an amino acid sequence essentially as set forth in SEQ ID NO:10.

16. The isolated GB1 domain polypeptide of claim 4, further comprising a mutation at an asparagine 35 residue of a native GB1 domain polypeptide, the mutation comprising an amino acid substitution of the asparagine 35 residue.

17. The isolated GB1 domain polypeptide of claim 16, wherein the mutation comprises substitution of the asparagine 35 residue with a comparatively non-polar amino acid residue.

18. The isolated GB1 domain polypeptide of claim 17, wherein the non-polar amino acid residue is selected from the group consisting of alanine, valine, leucine and isoleucine.

19. The isolated GB1 domain polypeptide of claim 18, having an amino acid sequence essentially as set forth in SEQ ID NO:12.

20. The isolated GB1 domain polypeptide of claim 4, further comprising a mutation at a tryptophan 43 residue of a native GB1 domain polypeptide, the mutation comprising an amino acid substitution of the tryptophan 43 residue.

21. The isolated GB1 domain polypeptide of claim 20, wherein the mutation comprises substitution of the tryptophan 43 residue with a comparatively non-polar amino acid residue.

22. The isolated GB1 domain polypeptide of claim 21, wherein the non-polar amino acid residue is selected from the group consisting of alanine, valine, leucine and isoleucine.

23. The isolated GB1 domain polypeptide of claim 22, having an amino acid sequence essentially as set forth in SEQ ID NO:16.

24. The isolated GB1 domain polypeptide of claim 4, further comprising mutations at a threonine 35 residue and at a tyrosine 45 residue of a native GB1 domain polypeptide, the mutation comprising an amino acid substitution of the threonine 35 residue and of the tyrosine 45 residue.

25. The isolated GB1 domain polypeptide of claim 24, wherein the mutation comprises substitutions of the threonine 35 residue and the tyrosine 45 residue with a comparatively non-polar amino acid residue.

26. The isolated GB1 domain polypeptide of claim 25, wherein the non-polar amino acid residue is selected from the group consisting of alanine, valine, leucine and isoleucine.

27. The isolated GB1 domain polypeptide of claim 26, having an amino acid sequence essentially as set forth in SEQ ID NO:18.

28. The isolated GB1 domain polypeptide of claim 1, further characterized as immobilized to a solid phase support.

29. The GB1 domain polypeptide of claim 1, wherein the Fab and the Fc fragments are from an IgG from a warm-blooded vertebrate.

30. The GB1 domain polypeptide of claim 29, wherein the Fab and the Fc fragments are from an IgG from a mammal.

31. The GB1 domain polypeptide of claim 30, wherein the mammal is selected from the group consisting of human, mouse, pig, rat, ape, monkey, cat, guinea pig, cow, goat and horse.

32. An isolated nucleic acid molecule encoding a GB1 domain polypeptide which binds a Fab fragment of an IgG but does not bind a Fc fragment of an IgG.

33. The isolated nucleic acid molecule of claim 32, wherein the encoded polypeptide comprises an amino acid sequence selected from among SEQ ID NO's:6, 8, 10, 12, 14, 16, 18, 20, 22 and 24.

34. The isolated nucleic acid molecule of claim 33, further defined as comprising a GB1 domain polypeptide-encoding nucleic acid molecule selected from among SEQ ID NO's:5, 7, 9, 11, 15, 17, 19, 21 and 23.

35. The isolated nucleic acid molecule of claim 32, further defined as a DNA segment.

36. The isolated nucleic acid molecule of claim 32, further defined as positioned under the control of a promoter.

37. The isolated nucleic acid molecule of claim 32, further defined as a recombinant vector.

38. The isolated nucleic acid molecule of claim 37, wherein the vector is a recombinant expression vector.

39. A recombinant host cell comprising the isolated nucleic acid molecule of claim 32.

40. The recombinant host cell of claim 39, wherein the host cell is a procaryotic cell.

41. The recombinant host cell of claim 39, wherein the host cell is a eukaryotic cell.

42. A method of preparing a GB1 domain polypeptide which binds a Fab fragment of an IgG but does not bind a Fc fragment of an IgG, comprising: transforming a cell with isolated nucleic acid molecule of claim 32 to produce a GB1 domain polypeptide which binds a Fab fragment of an IgG but does not

bind a Fc fragment of an IgG under conditions suitable for the expression of the polypeptide.

43. A method for purifying Fc fragments of IgG's by affinity chromatography, the method comprising the steps of:

(a) contacting a sample comprising IgG Fc and Fab fragments with a GB1 polypeptide of claim 1, the GB1 domain polypeptide immobilized to a solid phase support, to immobilize the IgG Fab fragments to the solid phase support; and

(b) collecting the IgG Fc fragment remaining in the sample.

44. The method of claim 43, wherein the Fab and the Fc fragments are from an IgG from a warm-blooded vertebrate.

45. The method of claim 44, wherein the Fab and the Fc fragments are from an IgG from a mammal.

46. The method of claim 45, wherein the mammal is selected from the group consisting of human, mouse, pig, rat, ape, monkey, cat, guinea pig, cow, goat and horse.

47. A method for purifying Fab fragments of IgG's by affinity chromatography, the method comprising the steps of:

(a) contacting a sample comprising IgG Fc and Fab fragments with a GB1 polypeptide of claim 1, the GB1 polypeptide immobilized to a solid phase support, to immobilize the IgG Fab fragments to the solid phase support;

(b) collecting the IgG Fc fragment remaining in the sample; and

(c) eluting the IgG Fab fragments from the solid phase support to

give purified IgG Fab fragments in the eluate.

48. The method of claim 47, wherein the IgG Fab fragments bound to the immobilized GB1 polypeptide are eluted by washing the solid phase support with a buffer of about pH 3.5 to about pH 2.4 to give the Fab fragments in the eluate.

49. The method of claim 47, wherein the Fab and the Fc fragments are from an IgG from a warm-blooded vertebrate.

50. The method of claim 49, wherein the Fab and the Fc fragments are from an IgG from a mammal.

51. The method of claim 50, wherein the mammal is selected from the group consisting of human, mouse, pig, rat, ape, monkey, cat, guinea pig, cow, goat and horse.

52. A method for detecting IgG, a fragment of an IgG, or combinations thereof, in a fluid sample suspected of containing IgG, a fragment of an IgG, or combinations thereof, the method comprising the steps of:

(a) contacting the fluid sample with a binding substance comprising the GB1 polypeptide of claim 1, under conditions favorable to binding of IgG, a fragment of an IgG, or combinations thereof to the binding substance to form a complex therebetween; and

(b) detecting the complex by means of a label conjugated to the binding substance or by means of a labeled reagent that specifically binds to the complex subsequent to its formation.

53. The method of claim 52, wherein the binding substance is conjugated with a detectable label and wherein detecting step (b) comprises:

i) separating the complex from unbound labeled binding substance; and

ii) detecting the detectable label which is present in the complex or which is unbound.

54. The method of claim 53, wherein the fragments of the IgG are Fab and the Fc fragments are from an IgG from a warm-blooded vertebrate.

55. The method of claim 54, wherein the Fab and the Fc fragments are from an IgG from a mammal.

56. The method of claim 55, wherein the mammal is selected from the group consisting of human, mouse, pig, rat, ape, monkey, cat, guinea pig, cow, goat and horse.